Remarks

Claims 1-21 were pending in the subject application. By this Amendment, claims 1, 11, 15, and 21 have been amended and new claims 22-23 have been presented. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1-23 are currently before the Examiner for consideration. Applicant respectfully submits that these amendments will require no further search on the part of the Examiner and do not constitute new matter. Favorable consideration of the pending claims is respectfully requested.

It should also be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion. These amendments should not be construed as an indication of Applicant's agreement with or acquiescence to, the rejections of record. Applicant expressly reserves the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Applicant appreciates the Examiner's indication that the rejection under the obviousness-type double patenting has been withdrawn in view of applicant's submission of a terminal disclaimer with the last response.

Claims 1-21 have been rejected under 35 U.S.C. §112, first paragraph, as failing to convey to one skilled in the art that the inventor had possession of the claimed invention. More particularly, the Office Action states that "the specification does not disclose a genus of variants for a plurality of L-amino acids and glycine (part c) in the anabolic composition." Applicant respectfully traverses this ground for rejection to the extent that it might be applied to the claims as amended herein. *Applicant notes that a similar rejection with regard to the recitation of "a plurality of L-amino acids" was asserted in the Office Action dated January 11, 2008. Applicant subsequently amended the claims in the Amendment Under 37 CFR 1.111 filed May 12, 2008 and were informed in the following Office Action of August 26, 2008 that the rejection had been overcome.*

In an effort to expedite prosecution, claims 22-23 has been added to indicate that the composition comprises "a plurality of enantiomerically pure L-amino acids and glycine in molar ratios equivalent to that specified in the genetic code of a normal human tissue". Support for this

amendment can be found throughout the specification, for example at page 6, lines 18-21, page 21, lines 9-11 and page 24, lines 30-31. Applicant respectfully asserts that there are sufficient recitations throughout the specification of human tissues that can be treated with the compositions of the subject invention, which mimic the tissues to be treated. Further, it would be a matter of routine experimentation for a person skilled in the art to determine the molar ratios of a human tissue in need of treatment with the therapeutic compositions of the subject invention. Indeed, the amino acid composition and molar ratios of thereof within various human tissues are already known to those skilled in the art. For example, Wilkerson, V.A. "The Chemistry of Human Epidermis I: Amino Acid Content of the Stratus Corneum and Its Comparison to Other Human Keratins", *J. Biological Chemistry*, Vol. 107, p. 377, 1934 and Rothberg, S. *et al.* "The Amino Acid Composition of Protein Fractions from Normal and Abnormal Epidermis," *J. Investigative Dermatology*, Vol. 44, pp. 320-325, 1965 both teach specific information about the amino acid compositions of epidermis and various components thereof, copies of which are attached for review.

As the Examiner is undoubtedly aware, there is no requirement that a specification teach that which is well known in the art. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81 (Fed. Cir. 1986) citing *Lindemann Maschinenfabrik v. American Hoist and Derrick*, 221 U.S.P.Q. 481 (Fed. Cir. 1984), (". . . a patent need not teach, and preferably omits, what is well known in the art."). Applicant respectfully asserts that a person of ordinary skill in the art, having the benefit of the teachings of the subject specification, would be able to determine the amino acid composition of a human tissue for use with the subject composition.

Applicant now turns to the rejection of claims 1-21 on the basis that the claims contain subject matter which was not described in the specification so as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. The Office Action argues that subsection (c) of the independent claims is not supported by the as-filed specification because there is insufficient description of the whole genus of amino acid mixtures having a plurality of L-amino acids and glycine. In support of this position, the Office Action cites to *University of California v. Eli Lilly & Co.* Applicant submits that the facts of *Lilly* do not support the position of the Office Action. In *Lilly*, the court found that the specification at issue did not identify the sequence (structure) of any embodiment of DNA claimed therein. *See Eli Lilly,*

119 F.3d at 1567-68 (affirming a judgment that the claim requiring cDNA encoding human insulin was invalid for failing to provide an adequate written description where the specification described the human insulin A and B chain amino acid sequences encoded by the cDNA, but did not provide the nucleotide sequence for the cDNA itself). This same type of issue is discussed at M.P.E.P § 2163, also cited in the Office Action.

It is well-settled law that a description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description and has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263, 191 U.S.P.Q. at 97. In this case, it is submitted that the Office Action fails to establish why a person of skill in the art would not have recognized the disclosure as a description of the invention defined by the claims. While the Office Action cites to *Lilly* as support for the proposition that the claimed invention lacks adequate written description in the as-filed specification, Applicant submits that reliance on *Lilly* and the rationale for the decision of that case is flawed. As discussed above, the *Lilly* court held that a claim requiring cDNA encoding human insulin was invalid for failing to provide an adequate written description where the specification described the human insulin A and B chain amino acid sequences encoded by the cDNA, but did not provide the nucleotide sequence for the cDNA itself. In this application, however, the structures of the amino acids recited in the claims is (and has been) known; thus, the arguments regarding the written description issue are not germane to the invention claimed in this application. Indeed, the Federal Circuit held "in accordance with our prior case law, that (1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be met (as it is here) even where actual reduction to practice of an invention is absent; and (3) there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure". See *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366, 79 U.S.P.Q.2d 1001 (Fed. Cir. 2006).

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

In view of the foregoing remarks and amendments to the claims, Applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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FCE/gld
Attachments: Copy of Wilkerson, 1934
Copy of Rothberg *et al.*, 1965